

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13277



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

Page CFSAN

Form Approved OMB No. 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

95855

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A. Patient information

1. Patient identifier	2. Age at time of event: <u>32</u> or Date of birth: <u>[redacted]</u>	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight <u>190</u> lbs or ____ kgs
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B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input checked="" type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: <u>Became sick</u>	
3. Date of event (mo/day/yr) <u>01-07-99</u>	4. Date of this report (mo/day/yr) <u>01-08-99</u>

5. Describe event or problem

Purchase done on 11-20-97, however it was for a gift for Christmas. Which was given to him for a present. He took the supplement as directed and after awhile became ill, Headach, stomach sickness etc. I went to the [redacted] Mall where I purchased it with receipt & product. The girl told me since it was past the 30 days she told me she couldn't. I tried to explain about given it as a Christmas gift she refused.

6. Relevant tests/laboratory data, including dates

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7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

N/A

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 <u>metabolife 356</u>		#1	
#2		#2	
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 <u>1/2 Pills</u>		#1	
#2		#2	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
9. NDC # (for product problems only)		8. Event reappeared after reintroduction	
#1		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			

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D. Suspect medical device

1. Brand name <u>metabolife 356</u>		4. Operator of device	
2. Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
3. Manufacturer name & address <u>metabolife 356</u>		5. Expiration date (mo/day/yr) <u>08-01</u>	
6. Model #		7. If implanted, give date (mo/day/yr)	
catalog # <u>H819</u>		8. If explanted, give date (mo/day/yr)	
serial #			
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
[redacted]			
2. Health professional?	3. Occupation	4. Also reported to	
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	<u>Housewife</u>	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input checked="" type="checkbox"/> distributor	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and
Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT
return this form
to either of these
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business

Penalty for Private Use \$300

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

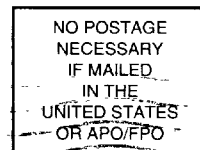
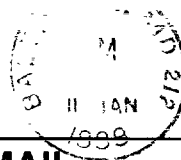
POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

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The FDA Medical Products Reporting Program

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